HASQARD Focus Group
Meeting Minutes
December 4, 2018

The meeting was called to order by Jonathan Sanwald, HASQARD Focus Group Chair at 2:06 PM on December 4, 2018 in Conference Room 308 at 2420 Stevens Center Place.

Those attending were: Jonathan Sanwald, HASQARD Focus Group Chair (Mission Support Alliance (MSA)), Cliff Watkins - Focus Group Secretary (Corporate Allocation Services, U.S. Department of Energy – Richland Operations Office (RL) Support Contractor), Linda Carr (Battelle – Pacific Northwest National Laboratory (PNNL)), Glen Clark (Washington River Protection Solutions (WRPS)), Fred Dunhour (ORP), Scot Fitzgerald (CH2MHILL Plateau Remediation Company (CHPRC)), Heather Medley (CHPRC), Anthony Nagel (CHPRC), Karl Pool, (PNNL), Geoff Schramm (WRPS), Paula Sellers (Waste Treatment Completion Contractor (WTCC)), Noe'l Smith-Jackson (Washington State Department of Ecology).

I. The Chair requested review and approval of the meeting minutes from the HASQARD Focus Group held on November 6, 2018. The draft minutes from the meeting were distributed and time was allowed for one final review. Hearing no comments on the draft meeting minutes, the minutes from the November 6, 2018 meeting were approved.

II. The HASQARD Focus Group has a standing agenda item to discuss the status of activities associated with the DOE Consolidated Audit Program – Accreditation Program (DOECAP-AP) at all HASQARD Focus Group meetings. This month, the following updates were discussed:

Glen Clark reported that he was not encouraged by the assessment report he received to document the assessment that was conducted at Eurofins by the Perry Johnson Laboratory Accreditation (PJLA). In contrast, the report provided by the American Association for Laboratory Accreditation (A2LA) to document their assessment at the General Engineering Laboratories (GEL) facility in Charleston, SC was much better. The HASQARD gap checklist that was provided by PJLA to document the Eurofins assessment appeared to be the one that was completed by the laboratory with no additions from PJLA other than findings that were acknowledged by the laboratory. Another concern was that the A2LA report did not include comments on the HASQARD gap checklist to document the objective evidence reviewed to support the determination of compliance with the requirement (e.g., data package number, calibrated weight set identification number). The WRPS reviewers of the AB's assessment reports expect to see objective evidence associated with acceptable assessment items and findings identified in the assessment. The CHPRC personnel present indicated they had not yet seen any of the AB's DOECAP-AP assessment reports except for one that was sent

out for the assessment conducted at GEL. Glen Clark suggested that all companies contracting to the laboratories assessed by the DOECAP-AP be reviewing the relevant reports and assessor's checklists produced and providing feedback to Steve Clark at DOE-HQ to ensure the Hanford needs for these reports are being met. Glen's general comment/observation regarding the DOECAP-AP reports he has reviewed so far is that, while they are not up to the standards and expectations for reports produced by the DOECAP audits that preceded implementation of the DOECAP-AP, they may be adequate to meet the needs of the Hanford contractors.

Paula Sellers asked who at Hanford is on routine distribution for the DOECAP-AP reports produced by the accrediting bodies (ABs). Heather Medley stated that she thought Steve Clark was supposed to be sending these reports out but CHPRC has not seen them. Jonathan Sanwald stated that there will be no routine distribution of the reports. However, Steve Clark has been very accommodating in providing them when requested. Recently, MSA requested a report from Steve and it was provided without issue. It was asked if there should be a central point of contact for receiving these reports at Hanford who could then distribute them to the interested parties within each company. Jonathan stated that the MSA AVS organization is currently keeping track of about 12 laboratories on the Evaluated Supplier List and is also trying to keep track of which laboratories are used by each company. Jonathan said that if Steve Clark was comfortable with sending the reports to one individual at Hanford, that individual could distribute the reports to the applicable contacts within the contractors. Paula Sellers asked if the reports are still classified as Official Use only (OUO). Jonathan stated that they are not OUO anymore, so Steve Clark can distribute them.

Jonathan Sanwald followed up on the issue of inadequate references to objective evidence in the reports. Jonathan asked if this will lead to a situation where the Hanford contractors need to follow-up by going to the laboratories to obtain a reference to the objective evidence. Glen Clark reiterated that all of the Hanford contractors need to be obtaining and reviewing the DOECAP-AP reports and assessor's checklists to see if they meet their needs and, if not, provide the feedback to Steve Clark. Jonathan Sanwald added that the same issue has occurred when MSA performs a third party review using the Energy Facility Contractor Group (EFCOG) supply chain shared audits found in the EFCOG Master Approved Supplier List (MASL) database. That is, sometimes a follow-up with the supplier is required to obtain adequate documentation of objective evidence.

Glen Clark stated a belief that the DOE-HQ personnel responsible for the DOECAP-AP (Debbie Rosano-Reece and Steve Clark) want to support the field as a customer service organization. The DOE-HQ personnel recognize the HASQARD Focus Group efforts and Glen believes they will take input from us seriously and act on it to get us what we need. Jonathan Sanwald

asked if we should be communicating with the DOE-HQ personnel individually or as a group. Glen Clark said that if we have an issue that the Focus Group agrees impacts all the companies, raising it as a group would probably be a good idea.

Jonathan Sanwald stated that there was one DOECAP-AP assessment conducted since the last HASQARD Focus Group meeting and asked if anyone present had been an observer at that assessment. Scot Fitzgerald said there was a DOECAP-AP assessment at Test America in Denver and he was there. Scot said it was an unusual assessment because DoD had accredited the laboratory in 2017. As a result, this assessment was a gap assessment to ensure the DOE only aspects of the DOECAP-AP accreditation would not impact the laboratory's accredited status. As a result, the entire assessment lasted only one and a half days. Scot reported that the AB assessors never went into the laboratory. The assessors conducted a desk evaluation in a conference room to assess the DOE gaps. Scot stated that he spent the majority of his time there assessing the HASQARD gap checklist items. Steve Clark was present at this assessment and was covering the Hazardous and Radioactive Materials Module (HRMM) that is part of the DOE accreditation requirements. This resulted in Steve having to go into the laboratories to complete his assessment activities. Glen Clark asked which AB was assigned this assessment. Scot stated that it was A2LA. Glen asked if the A2LA assessor completed a checklist for this assessment. Scot said he could not tell because the assessor was entering all observations on a lap top computer. So, it was not clear if a checklist was being used or not.

Heather Medley asked if any of the DOECAP-AP assessments to date have been "full accreditation" assessments as opposed to "gap" assessments done to fill in the gaps between DoD accreditation under the QSM and DOECAP-AP accreditation which requires DOE's requirements to be evaluated.
Glen Clark stated that the Columbia Basin Analytical Laboratory (CBAL) assessment was a full-blown accreditation assessment. Glen said he did not observe the CBAL assessment. Scot Fitzgerald stated that he observed the Test America Richland assessment. The AB did not send a radiochemistry subject matter expert to audit the radiochemistry analyses as part of this assessment. The AB sent an assessor with some radiation measurements experience but not a lot of it. This assessor was very open to Scot's feedback and suggestions as the assessment progressed.

Glen Clark stated that he believes it will be more important for the Hanford contractors to send observers on the DOECAP-AP assessments in 2019 because more full-blown assessments will be done that year than were done in 2018 (when most were gap assessments). It will be interesting to see how the assessors and laboratories follow-up on corrective actions required as a result of the gap assessments conducted in 2018. Scot Fitzgerald added that if a full assessment was conducted at a laboratory in 2018, the AB will do a desk

evaluation of the laboratory in 2019. Glen Clark agreed that this was his understanding also and added that a laboratory could receive a visit from the AB for a surveillance during the year after a full-blown assessment if necessary.

Jonathan Sanwald asked Scot if Test America had completed a HASQARD gap checklist ahead of his presence at the laboratory. Scot said they had completed the checklist but it lacked detail. Scot said in some cases he spent some time in the laboratory's procedure where they thought a HASQARD requirement was addressed and determined the laboratory was not understanding the intent of the requirement. As a result, Scot would look in other procedures and often found a different place where the requirement was addressed.

It was also stated that Jim Douglas is in St. Louis this week to observe the DOECAP-AP assessment at Test America – St. Louis. Cliff Watkins asked if those present had heard that Test America had been purchased by Eurofins. The Focus Group members present confirmed that Eurofins had purchased Test America. Cliff stated he had been asked by RL environmental personnel if the ownership of the laboratory by a foreign owned business would be an issue. Heather Medley stated that Test America was Chinese owned before the sale to Eurofins. Therefore, it is not anticipated that the sale of Test America to Eurofins will be an issue.

III. The status of production of Revision 5 of HASQARD was discussed.

The Chair of the Volume 1 subcommittee, Paula Sellers, asked Glen Clark to present the rationale behind the extensive revision that has been made to Volume 1. The revised document was displayed via overhead projector and Glen began to discuss the bases for the revision.

Much of Volume 1 has been eliminated based on the fact that the majority of the administrative requirements specified in HASQARD are covered by the Hanford Contractor's QA programs and HASQARD creates a new set of requirements that are not adding value. The philosophy behind the revision is that the HASQARD is creating an additional set of redundant requirements that Hanford contractors must assess themselves to. Noe'l Smith-Jackson requested the view of the electronic document being displayed be changed to show the amount of strike out (deletions). When this was displayed, the majority of the Focus Group felt like they would need some time to evaluate this proposed revision. Anthony Nagel added that it is possible that much of the deleted text could be saved and inserted in a guidance document that would not represent requirements but would aid in consistent application of the administrative requirements relevant to analytical services.

Glen Clark highlighted the fact that, if accepted, the language in Volume 1 of

HASQARD would reference the fact that laboratories derive QA requirements from the DoD/DOE QSM. Glen mentioned that Tricia Wood, while not present at this meeting, has raised concerns whether the 222S Laboratory could comply with all of the requirements specified in the QSM. Glen Clark has held discussion with Tricia on this where he advised her to build in enough flexibility in the laboratory's QA program to justify exceptions to QSM requirements that cannot be met.

Jonathan Sanwald asked if PNNL would also have trouble implementing HASQARD if the QSM was referenced as the basis of QA requirements. Karl Pool replied that he could not give a complete response to that question at this meeting because this is the first he has seen of the proposed revision. Karl stated that he needs to see the language being proposed, look at the QSM and address the flow-down of requirements. Jonathan acknowledged this and agreed that the on-site laboratories will need some time to evaluate the QSM requirements. Glen Clark agreed saying that the HRMM requirements are an example of requirements present in the QSM that are not addressed by HASQARD. Another major QC acceptance criteria requirement in the QSM is in relation to continuing calibration verification (CCV) analysis. When a CCV fails the QC acceptance criteria, the Appendix B tables in the QSM specify that corrective action be performed followed by two consecutive, acceptable CCV analyses. This is a unique requirement associated with the QSM since most analytical laboratories simply require one successful CCV analysis to continue analyzing samples. Glen added that this requirement came from The National Environmental Laboratory Accreditation Conference Institute (TNI) requirements but was eliminated from TNI requirements in the 2016 update. Therefore, this particular requirement may be removed from the QSM in Revision 6.0 (scheduled for release in January 2021). Scot Fitzgerald agreed and added that other differences between the QSM and HASQARD are in some of the QC acceptance criteria and radiochemistry calculation specifications which the QSM derives from the Multi-Agency Radiological Laboratory Analytical Protocols Manual (MARLAP). Anthony Nagel stated that perhaps the 222S Laboratory (and others) that cannot abide by the QSM produce a "known exceptions" table to show how they are implementing the QSM. That table could be provided to clients of the laboratory to determine the impacts. Glen Clark agreed saying that revising HASQARD to say that the QSM is used to specify laboratory QA requirements will have no impact on the commercial laboratories, but will impact 222S and that impact needs to be known and addressed. Cliff Watkins requested confirmation that the DOECAP-AP has no intention of coming to accredit on-site contractor laboratories. The Focus Group members present indicated that was true. Cliff then requested confirmation that supplier evaluation of the 222S laboratory would occur by a group of Hanford contractor personnel, led by the MSA AVS organization, conducting an audit to the QSM. The Focus Group members present confirmed that this would be the plan for approving the 222S laboratory after implementation of HASQARD Revision 5. Glen Clark added

that Hanford contractors could use the old DOECAP audit checklists to conduct the 222S laboratory supplier evaluation audit because they are still very comprehensive to the QSM requirements.

Glen Clark discussed the HASQARD gap checklist that is in the QSM Revision 5.2 as an appendix. Glen has gone over the HASQARD gap checklist to determine the source of requirements specified. This provides a technical basis for the HASQARD gap checklist. The plan will be to provide these technical drivers for the requirements to the QSM data quality workgroup (DQW) to support incorporating the HASQARD gap requirements as base requirements in the QSM Rev 6.0. If the QSM incorporates all of the HASQARD gap requirements, the gap checklist goes away and compliance with the QSM would equate to compliance with HASQARD. Jonathan Sanwald clarified that this won't occur until Rev 6.0 which is due to be issued in January 2021. Glen Clark confirmed that this is the current schedule for issuance of QSM Revision 6.0. The QSM Revision 5.2 is scheduled to be released the end of December 2018. Glen submitted some comments and was told that they would not be addressed until Revision 6, which is problematic.

Karl Pool commented that PNNL is the receiver of requirements for analytical services from Hanford contractor clients. He was curious how these requirements would be worded if HASQRD is revised as proposed. Jonathan Sanwald stated that it would be no different than it is done now. Jonathan said the SOWs (or equivalent documents) that PNNL works to would not have to change except for which revision of HASQARD is being cited as the source of requirements. Karl replied that it will be much different due to the new requirements. Karl was curious whether HASQARD Volume 4 will be deleted. Glen Clark stated that he has not been involved in the Volume 4 revision efforts but does not think the Volume will go away. The requirements may be greatly reduced with references to the QSM. However, how Volume 4 will be revised is still in development.

Noe'l Smith-Jackson asked if the QSM revision that will include the HASQARD gap checklist would be Revision 5.2 and if that was not scheduled to be available until January 2020. Glen stated that Revision 5.2 of the QSM with the HASQARD gap checklist included as an appendix is scheduled to be issued January 2019. Having the HASQARD gap checklist in the QSM will allow the ABs to issue findings when HASQARD requirements are not being met. Noe'l then asked about what the QSM revision scheduled for January 2021 will involve. Glen replied that the goal is to get all of the HASQARD gap requirements addressed as standard requirements within the QSM, or get them removed them from HASQARD, such that no HASQARD gap checklist appendix is needed in the document.

Karl Pool stated he is still curious about what the future will look like. That is, are there QSM requirements that won't apply to the on-site laboratories?

Glen Clark stated that flexibility where the QSM requirements are more stringent than the current HASQARD requirements need to be addressed by the Volume 4 revision. Heather Medley added that the flexibility or relief from QSM requirements could also be specified in whatever work order document a Hanford contractor uses to obtain services form an on-site laboratory. Karl agreed and stated that his concern will be clients of the laboratory will just say "follow HASQARD" and there may be QSM expectations for commercial laboratories in HASQARD that the on-site laboratories cannot meet. Glen concurred saying there will be QSM requirements that don't matter to us and we will need to allow relief from them for the on-site laboratories. This means the Focus Group will need to know what these unachievable requirements are. The sample storage temperature monitoring and immediate, automated notification of a temperature excursion requirement in the QSM is an example of a requirement that can't be met at the 222S laboratory.

Glen Clark acknowledged that it will take some work to determine where the new requirements to HASQARD will appear as a result of deferring to the QSM as the source of all requirements. Glen stated a belief that between the laboratory QA Plans and the material in Volume 4, we should be able to address the new requirements such that the on-site laboratories are minimally impacted. Glen also stated that we need to get the language in HASQARD developed well so that every revision to the QSM (which can and will be revised more often than HASQARD) does not give us issues. Cliff Watkins stated that before we issue Revision 5, these issues need to be known or some standard language on the mechanism on-site laboratories may use to be relieved from a QSM requirement needs to be written in HASQARD. Noe'l Smith-Jackson stated that perhaps the old deminimus process could be used to provide requirements relief to on-site laboratories.

Jonathan Sanwald stated that we have done lots of analyses to determine requirements that are in HASQARD that are not present in the QSM, but what about QSM requirements that have never been in HASQARD? Glen Clark stated that there have been some partial analyses done to determine QSM requirements that are in addition to the HASQARD requirements but nothing completely done.

Cliff Watkins asked what the next step should be. Glen Clark stated the on-site laboratories need to review the QSM and determine requirements that they cannot meet due to operations restrictions. Relief from these requirements, for on-site laboratories only, need to be addressed in HASQARD Volume 4.

Jonathan Sanwald asked Noe'l Smith-Jackson what her unofficial impression of the ideas being discussed were. Noe'l stated that "in theory" these ideas should be able to be implemented. This will especially be true as long as the

DOECAP-AP ABs audit to the HASQARD gap checklist at the commercial laboratories. However, if the Hanford representatives observing the DOECAP-AP assessments believe the ABs are not implementing the HASQARD gap checklist properly, the State would likely not support the current plan. Jonathan Sanwald stated this is clearly a slowly maturing process that should work for us in the end.

Cliff Watkins asked if he should distribute the electronic version of HASQARD Volume 1 that was being displayed at the meeting to all Focus Group members for review and comment. Glen Clark said, yes, it is time for all Focus Group members to review this version of Volume 1.

The Focus Group turned its attention to the completed draft of Revision 5 to Volume 2 of HASQARD. The Volume 2 writing committee Chair, Geoff Schramm, used a display of the electronic version of the current revision to discuss comments his committee has received so far. Geoff indicated that after the HASQARD Focus Group Secretary sent the draft out for review approximately two weeks ago, he has received comments from only two or three people.

The Focus Group spent a great deal of time discussing comments from Fred Dunhour. One of the comments pointed out that all of the material presented in Volume 2 is a result of combining best practices from several EPA guidance documents. This results in making requirements out of what was originally issued as guidance. Another comment was that if the contractors want to implement these guidance statements as requirements, they should do it by implementing them in the contractor's environmental QA plans and or procedures. If the Focus Group concurred with that view, Fred commented that there is no purpose for HASQARD Volume 2 and it should be deleted.

Noe'l Smith-Jackson stated that elimination of Volume 2 and reliance on the contractors to specify sampling protocols in their company plans and procedures would likely result in a lack of between-contractor consistency in the way the contractors conduct field sampling.

Anthony Nagel commented that while the statements present in HASQARD are derived from guidance documents, by contract language and its title HASQARD is a requirements document.

Glen Clark acknowledged the conversation and added that while working on volume 2, the team has spent some time working out those statements that are requirements from those that can be used as guidance (i.e., invoke the verb "should" as opposed to "shall"). Glen stated that they actually found some instances where "should" statements in HASQARD should be "shall" statements due to drivers being referenceable for the requirements.

Geoff Schramm stated that while HASQARD is a requirements document, most requirements in Volume 2 were derived from EPA guidance documents. The Volume 2 team agreed that if a driver could be found for the shall statements, the statement would be retained with a shall (i.e., as a requirement). Glen Clark stated that he considered SW-846 and the EPA CERCLA Contract Laboratory Program (CLP) Sampler's Guide as requirement drivers because SW-846 and CERCLA were referenced in the TPA. Glen Clark also stated that most of the requirements in HASQARD Volume 2 were inserted when Chris Sutton revised Volume 2 and used statements from either SW-846 or the EPA CERCLA Contract Laboratory Program (CLP) Sampler's Guide in developing the HASQARD requirements present in the current revision of Volume 2.

The Focus Group spent some time discussing the process for review and approval of sampling and analysis plans (SAPs) and the QA Project Plan (QAPjPs) associated with the SAPs. The question being posed was, if HASQARD Volume 2 were to be eliminated, would EPA and/or Ecology have the opportunity to ensure consistency and appropriate sampling methods are used by reviewing and commenting on the SAP and associated QAPjP? No resolution to this question could be concluded with those assembled as it represented a policy question outside the authority of the HASQARD Focus Group.

Glen Clark recalled the history of the development of HASQARD stating that it was originally developed to comply with the newly implemented TPA requirements and followed the EPA document QAMS-005/80 to do that. Cliff Watkins added that, while he was not here at the time, he believes HASQARD was written because DOE knew that it would have several contractors working on environmental cleanup through the years and wanted a baseline set of expectations to guide the manner in which that work would be accomplished. By developing HASQARD, and referencing it in contracts, DOE knew its contractors would be working to requirements that met the expectations of the regulators that participated in the review of HASQARD as it was being developed. Noe'l Smith-Jackson concurred with that view adding that the HASQARD was developed to ensure consistency across contractors.

Geoff Schramm stated that many of the requirements in Volume 2 were added by Chris Sutton and were derived from the EPA CLP Samplers Guide. Geoff stated that considering the CLP Samplers Guide as requirements may result in issues for some companies (e.g., when highly radioactive samples are being collected). Noe'l Smith-Jackson stated that she agrees with the need for flexibility when it comes to sampling highly radioactive media, but believes that eliminating Volume 2 entirely would not be beneficial.

Fred Dunhour clarified one of his comments saying that he believes it should

not be our intent to take what has been initially provided as guidance by EPA and making them requirements by using the verb "shall." Glen Clark stated that SW-846 is a guidance document, but if there is not a good reason to implement the guidance found in that document, then we need the company's QA programs to implement alternative requirements. Fred agreed adding that there is no basis for changing EPA "should" statements into Hanford "shall" statements. Glen Clark agreed but added that the shall statements in HASQARD were agreed to as best practices and acceptable requirements for all companies to implement. However, moving forward, perhaps one company will not want to ship samples in accordance with CERCLA sampling guide requirements and should be afforded that flexibility by changing some "shall" statements in HASQARD to "should" statements.

Geoff Schramm stated that if we begin to look at HASQARD Volume 2 as a guidance document and not a requirements document by changing all "shall" statements to "should" statements, there are no requirements and all contractors would end up doing what they want through their QA programs. This would create a free for all. Scot Fitzgerald added that if all HASQARD statements were coined as "shoulds" then there would be nothing to audit a sampling program to. However, there needs to be some leniency to allow contractors to implement a program that makes the most sense for their situation. Glen Clark stated that he agrees with Noe'l in that there needs to be some kind of base set of requirements that a contractor can deviate from in individual project SAPs and/or QAPjPs. Heather Medley added that if all standardized requirements are eliminated, there would be no continuity in how samples are collected when contracts are re-awarded to new contractors at Hanford. Karl Pool added that the intent of incorporating requirements from guidance documents needs to be evaluated and that's what the HASQARD Focus Group has always done to reach concurrence on the guidance that will be implemented as a standard operating procedure across Hanford contractors. Cliff Watkins asked if Volume 2 should be revised to indicate that it presents a standard set of practices that are implemented by default unless a project's QAPjP implements alternative practices either by reference to another company procedure or directly in the QAPjP. This standard set of practices could all then be stated as "should" statements.

Glen Clark commented that data quality project plans should be defined in the document and Geoff Schramm agreed to add that definition.

Jonathan Sanwald wrapped up the review of the draft of Revision 5 of Volume 2 saying we have resolved 80-90% of the comments received.

IV. In the way of new business, Glen Clark requested that the next HASQARD Focus Group meeting be moved to one week later to allow greater attendance at the meeting. The Secretary agreed to get the meeting rescheduled.

Hearing no additional new business, Jonathan Sanwald adjourned the meeting at 4:07 PM.

The next meeting of the HASQARD Focus Group will be at 2:00 PM on January 22, 2019 in Conference Room 308 at 2420 Stevens Center Place.